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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,837	12/07/2005	Soojin Lee	CMT0016US	2897

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EXAMINER	
NGUYEN, QUANG	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
04/10/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/530,837	LEE ET AL.	
	Examiner	Art Unit	
	QUANG NGUYEN, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-11 and 24-32* is/are pending in the application.

4a) Of the above claim(s) *24-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 5-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 12/29/08 was entered.

Amended claims 1, 5-11 and 24-32 are pending in the present application.

Claims 24-32 were withdrawn previously from further consideration because they are directed to non-elected inventions.

Accordingly, amended claims 1 and 5-11 are examined on the merits herein.

Priority

The present application is a 371 of PCT/KR03/02161, filed on 10/16/2003, which claims benefit of 60/419,911, filed on 10/18/2002; 60/419,912, filed on 10/18/2002; 60/420,088, filed on 10/18/2002; 60/434,243, filed on 12/16/2002; 60/434,278, filed on 12/16/2002; and 60/438,278, filed on 01/03/2003.

Upon review of the specifications of the above provisional applications and comparison with the specification of the present application, it is determined that with respect to the elected invention claims 1-11 are only entitled **at best to the effective filing date of 12/16/2002** because SEQ ID NOs. 1-4 were first disclosed in the specification of the provisional application 60/434,278.

Claim Objections

Claims 9 and 11 are objected to because of the phrases "A host cell....prokaryotic host cells and eukaryotic host cells" and "said host cell...prokaryotic

host cells and eukaryotic host cells", respectively. Please be consistent with either a host cell or host cells. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Amended claims 7 and 10-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Tsuji et al (US 6,015,680) as evidenced by Lee et al. (US 2006/0168670). ***This is a new ground of rejection.***

Claim 7 is drawn to a host cell transformed to contain the nucleic acid molecule of claim 1. Claims 10-11 are directed to a method for producing a polypeptide comprising culturing a host cell transformed with the nucleic acid molecule of claim 1 under conditions in which the protein encoded by said nucleic acid molecule is expressed.

Tsuji et al already disclosed a method comprising the step of culturing an established lung adenocarcinoma cell line such as the human Calu-3 (transformed

human cells) in RPMI 1640 medium or MM medium (see at least col. 3, lines 60-63 and col. 8, lines 22-26). The human lung adenocarcinoma Calu-3 cells would inherently express or contain the nucleic acid molecule of claim 1 as evidenced by the teachings of Lee et al which disclosed that lung adenocarcinoma cells overexpressed human LFG1 sequences (SEQ ID NO:1 or 3) 5.77 X relative to normal lung cells (see at least example 2 and Table 1).

Accordingly, the teachings of Tsuji et al meet every limitation of the instant claims as broadly written.

Amended claims 1 and 5-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Venter et al. (WO 02/068579). ***This is a new ground of rejection.***

The embodiment (b) of independent claim 1 is directed to an isolated nucleic acid molecule comprising **the complement of a nucleic acid molecule of (a)**, the following rejection is applied because its scope encompasses **the compliment of any nucleic acid molecule of (a), not necessarily limited to the compliment of the isolated nucleic acid molecule of (a) as argued by Applicants** (e.g., a fragment of the isolated nucleic acid molecule of (a)).

Venter et al already disclosed a human transcript sequence comprising SEQ ID NO: 2062 that is 72.4 % (about 75% nucleotide sequence identity) to the entire SEQ ID NO:1 or 73.7% to the entire SEQ ID NO: 3 of the present invention (see at least SEQ ID NO: 2062; page 3, first two full paragraphs; Summary of the Invention; page 14, first full paragraph). Venter et al further taught that the disclosed human coding sequences will

be of great value for a variety of commercial purposes, including the production of encoded proteins and the development of therapeutic proteins and protein targets for human intervention typically involves identifying a protein that can serve as a target for the development of a small molecule modulator (see at last page 10, lines 18-30). The isolated nucleic acid molecule can be fused to other coding or regulatory sequences or contained in a vector or be maintained in heterologous host cells (page 17, line 27 continues to line 10 of page 18). Since the isolated nucleic acid molecule encoding the human transcript sequence comprising SEQ ID NO:2062 falls within a broad breadth of a nucleic acid molecule of (a) and it also contains the corresponding complementary strand or the complement, the teachings of Venter et al meet every limitation of the instant broad claims.

Therefore, the reference anticipates the instant claims as broadly written.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended claims 1, 6 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venter et al. (WO 02/068579) in view of Kuo et al. (EP 0150735). ***This is a new ground of rejection.***

Once again, it is noted that the embodiment (b) of independent claim 1 is directed to an isolated nucleic acid molecule comprising **the complement of a nucleic acid molecule of (a)**, the following rejection is applied because its scope encompasses **the compliment of any nucleic acid molecule of (a), not necessarily limited to the compliment of the isolated nucleic acid molecule of (a) as argued by Applicants** (e.g., a fragment of the isolated nucleic acid molecule of (a)).

Venter et al already disclosed a human transcript sequence comprising SEQ ID NO: 2062 that is 72.4 % (about 75% nucleotide sequence identity) to the entire SEQ ID NO:1 or 73.7% to the entire SEQ ID NO: 3 of the present invention (see at least SEQ ID NO: 2062; page 3, first two full paragraphs; Summary of the Invention; page 14, first full paragraph). Venter et al further taught that the disclosed human coding sequences will be of great value for a variety of commercial purposes, including the production of encoded proteins and the development of therapeutic proteins and protein targets for human intervention typically involves identifying a protein that can serve as a target for

the development of a small molecule modulator (see at last page 10, lines 18-30). The isolated nucleic acid molecule can be fused to other coding or regulatory sequences or contained in a vector or be maintained in heterologous host cells (page 17, line 27 continues to line 10 of page 18).

Venter et al do not teach specifically the use of either prokaryotic or eukaryotic host cells comprising SEQ ID NO: 2062 or a method for producing a polypeptide comprising culturing a host cell transformed with SEQ ID NO: 2062, even though the reference discloses explicitly that the disclosed human coding sequence will be of great value for a variety of commercial purposes including the production of the encoded protein.

However, at the effective filing date of the present application Kuo et al already disclosed at least a method for the production of a heterologous protein, namely human Factor VIIIC, precursors and subunits thereof, by expression in a microorganism such as *E. Coli*; *B. subtilis* or a mammalian tissue culture cell such as COS cells, CV-1 cells (see at least Summary of the Invention on page 2; page 13, lines 6-17; page 15, lines 6-19).

Accordingly, it would have been obvious for an ordinary skilled artisan to modify the teachings of Venter et al by also utilizing a prokaryotic host cell or a eukaryotic host cell for expressing a protein encoded by the human transcript comprising SEQ ID NO:2062 in light of the teachings of Kuo et al.

An ordinary skilled artisan would have been motivated to carry out the above modification because a recombinant protein expression utilizing either a prokaryotic or a

eukaryotic host cell is well known and well established in the prior art as shown at least by the teachings of Kuo et al which taught successfully the expression of human Factor VIIIC, precursors and subunits thereof in a microorganism or a mammalian tissue culture cell.

An ordinary skilled artisan would have a reasonable expectation of success in light of the teachings of Venter et al., Kuo et al., coupled with a high level of skill of an ordinary skilled artisan in the relevant art.

Since the isolated nucleic acid molecule encoding the human transcript sequence comprising SEQ ID NO:2062 of Venter et al. falls within a broad breadth of a nucleic acid molecule of (a) and it also contains the corresponding complementary strand or the complement, the combined teachings of Venter et al and Kuo et al meet every limitation of the instant broad claims.

Therefore, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Conclusions

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/QUANG NGUYEN/
Primary Examiner, Art Unit 1633